

Remarks

By this amendment claim 2 is cancelled. No new claims are added. Claims 1, 3, and 5 are amended.

Rejections

All the pending claims were rejected as being shown or suggested by the teaching of one or more cited publications.

Reconsideration of the claims as amended and withdrawal of the rejection are respectfully requested.

Claim 1 has been amended to call for a sustained-release tablet comprising caffeine and poly(ethylene oxide), as recited in original claim 5. Such a tablet is beneficial for the reasons discussed in the specification.

Claims 1 and 5 were rejected as allegedly being taught by US 2003/0175326 A1 (Thombre). Applicants respectfully assert that the rejection should be withdrawn from Claim 1 as amended to include the limitation from Claim 5.

Thombre discloses caffeine as a pharmaceutically active agent, but only in a list of hundreds of other pharmaceutically active agents. The list is a veritable catalog of medicaments that one might wish to give to a companion animal.

Thombre also has numerous examples, beginning at paragraph [0088], of controlled release matrix tablets formulations, some of which include poly(ethylene oxide).

But just because one document mentions two components of the presently claimed invention, it does not follow that the invention of Claim 1 is shown or suggested by Thombre.

Applicants can find no example in Thombre where caffeine and poly(ethylene oxide) were combined to provide a sustained-release tablet, and cannot find any other indication that Thombre tested or even contemplated such a composition. All of Thombre's meaningful example compositions appear to contain carprofen, not caffeine, as the pharmaceutically active agent.

Dr. Thombre makes no pretence of teaching specific combinations of pharmaceutically active agents and controlled release matrix materials. His purpose, the incorporation of a palatability agent, is evident from paragraph [0011] of the publication:

[0011] Accordingly, there is a need for a controlled release dosage form that can be orally administered to a companion animal, which form can include a palatability agent and be chewed by the animal or divided without significant loss of the controlled release effect.

When all the possible pharmaceutically active agents and controlled release matrix materials mentioned in Thombre are considered, one might contemplate thousands of possible tablet compositions. Thus, at most, Thombre discloses an enormous genus from which a person might come up with combinations to try.

In this genus-species context, the Federal Circuit in Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc., 81 USPQ2d 1001, 1013 (Fed. Cir. 2006) recently stated:

“When a reference discloses a class of compounds, *i.e.*, a genus, a person of ordinary skill in the art should be able to “at once envisage *each member* of th[e] . . . class” for the individual compounds, *i.e.*, species, to be enabled. *In re Petering*, 301 F.2d 676, 681 [133 USPQ275] (C.C.P.A. 1962). If the members cannot be envisioned, the reference does not disclose the species and the reference is not enabling.”

In Impax Laboratories the Federal Circuit upheld the district court’s determination that the claimed compound was not anticipated when it “is just one of *hundreds* of compounds of formula I” in the prior art reference (emphasis added). MPEP §2131.02 further instructs that “anticipation can only be found if the classes of substituents are sufficiently limited or well delineated.”

As previously mentioned, the Thombre genus encompasses thousands of possible compositions. A person of ordinary skill in the art reading Thombre would not have at once envisioned the specific composition of pending claim 1 from the thousands of possible compounds encompassed by the generic teaching of Thombre. Accordingly, the generic disclosure in Thombre does not anticipate the composition of pending Claim 1.

Nor is Claim 1 obvious from the teachings of Thombre:

“[Where a] statement is of a type that gives only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it . . . [s]uch a suggestion may make an approach ‘obvious to try’ but it does not make the invention obvious.” *Ex parte Obukowskz*, 20 USPQ2d 1063, 1065 (U.S. Pat. and Trademark Off. Bd. of Pat. App. & Interferences 1993) (*citations omitted*).

General lists of ingredients that could be combined to produce thousands of compositions, such the lists presented in Thombre, to not provide the required specificity, so no *prima facie* case of obviousness can be established against Applicants' Claim 1.

It is therefore requested that the rejection of Claim 1 be withdrawn. And because all the other elected claims depend from Claim 1, all the remaining elected claims should be allowed.

(Claim 1 also was rejected based on the teachings of WO 02/067905 A1 (Gutierrez-Rocca). This rejection is moot in view of the amendment of Claim 1.)

Claim 11 additionally should be allowed because the use of kavalactone with caffeine in a sustained release system is not suggested by the cited US 005977120 A (Giles, Jr.). And adding yet one more material, kavalactone, to the thousands of compositions of the Thombre genus, would not suggest the particular invention of pending Claim 11.

Claim 19 also should be allowed because the claimed donut-shaped tablet is nowhere suggested by the cited publications. This tablet of Claim 19 is particularly advantageous for the delivery of caffeine, as explained in the specification at paragraphs [0050] – [0051].

Conclusion

The application is now in condition for allowance. Should there be any questions regarding this application, the Examiner is invited to contact the undersigned at the telephone number shown below.

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